

109TH CONGRESS
1ST SESSION

H. R. 801

To amend titles XVIII and XIX of the Social Security Act to provide for coverage under the Medicare and Medicaid Programs of certain screening procedures for diabetic retinopathy, and to amend the Public Health Service Act to establish pilot programs to foster such screening, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 15, 2005

Mr. COOPER (for himself, Mr. HALL, Mrs. MCCARTHY, Mr. McDERMOTT, Mr. McNULTY, Ms. MILLENDER-McDONALD, Mr. PAYNE, Mr. RANGEL, Mr. SPRATT, Mr. FORD, Mr. TANNER, Mr. TOWNS, Mr. WILSON of South Carolina, Mr. OWENS, Mr. DAVIS of Tennessee, and Mr. STARK) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend titles XVIII and XIX of the Social Security Act to provide for coverage under the Medicare and Medicaid Programs of certain screening procedures for diabetic retinopathy, and to amend the Public Health Service Act to establish pilot programs to foster such screening, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Diabetic Retinopathy
3 Prevention Act of 2005”.

4 **SEC. 2. FINDINGS.**

5 The Congress finds as follows:

6 (1) Type 2 Diabetes affects 17,000,000 Ameri-
7 cans, with over 1,000,000 new cases diagnosed each
8 year. Type 1 Diabetes affects over 1,000,000 Ameri-
9 cans, with over 13,000 new cases diagnosed each
10 year. Diabetes costs the nation an estimated
11 \$138,000,000,000 per year.

12 (2) Diabetic retinopathy is the most common
13 complication resulting from diabetes, and causes
14 degradation in visual acuity and eventual blindness.
15 Diabetic retinopathy is the leading cause of blind-
16 ness in people aged 20 to 74, and up to 24,000 dia-
17 betics become legally blind each year.

18 (3) During the first two decades of disease,
19 nearly all patients with Type 1 and over 60 percent
20 of patients with Type 2 Diabetes develop diabetic
21 retinopathy, and the risk of diabetic retinopathy in-
22 creases with the duration of diabetes. Onset of Type
23 2 diabetes is today occurring at younger ages, which
24 will increase the prevalence of diabetic retinopathy
25 in the future.

1 (4) Clinical trials have demonstrated that early
 2 detection and treatment of diabetic retinopathy can
 3 reduce vision loss by 90 percent, and remote assess-
 4 ment of diabetic retinopathy has the potential to
 5 reach large numbers of diabetic patients who live in
 6 rural, remote or underserved areas and who lack
 7 geographical or financial access to regular, in-office
 8 eye examinations by eye specialists.

9 **SEC. 3. MEDICARE COVERAGE OF REMOTE ASSESSMENT OF**
 10 **DIABETIC RETINOPATHY.**

11 (a) COVERAGE.—Section 1861 of the Social Security
 12 Act (42 U.S.C. 1395x) is amended:

13 (1) in subsection (s)(2)—

14 (A) in subparagraph (Y), by striking
 15 “and” at the end;

16 (B) in subparagraph (Z), by adding “and”
 17 at the end; and

18 (C) by inserting after subparagraph (Z)
 19 the following new subparagraph:

20 “(AA) remote assessment of diabetic retinop-
 21 athy (as defined in subsection (bbb));”; and

22 (2) by adding at the end the following new sub-
 23 section:

1 “Remote Assessment of Diabetic Retinopathy

2 “(bbb) The term ‘remote assessment of diabetic ret-
3 inopathy’ means a diagnostic examination of the retina for
4 the purpose of early detection of diabetic retinopathy
5 that—

6 “(1) is provided not more frequently than on an
7 annual basis to an individual who has been diag-
8 nosed with diabetes;

9 “(2) meets technical standards set forth by the
10 Secretary (which shall be determined in consultation
11 with industry and practitioner groups with expertise
12 in ophthalmology, ophthalmic imaging, telemedicine,
13 or related fields);

14 “(3) is furnished via a telecommunications sys-
15 tem by a physician (as defined in subsection (r)), a
16 practitioner (described in section 1842(b)(18)(C) of
17 this title), or a non-physician technician deemed to
18 be qualified by the Secretary under the regulations
19 promulgated pursuant to this Act, to an eligible pa-
20 tient enrolled under this part, notwithstanding that
21 the individual physician or practitioner providing the
22 service is not at the same location as the beneficiary;
23 and

1 “(4) is conducted under the supervision of a
2 board-certified ophthalmologist with retinal fellow-
3 ship training.”.

4 (b) PAYMENT NOTWITHSTANDING LIMITATION ON
5 STORE AND FORWARD TECHNOLOGY.—Notwithstanding
6 any limitations to the contrary that are set forth in section
7 1834(m)(1) of the Social Security Act (42 U.S.C.
8 1395m(m)(1)), the amendments made by subsection (a)
9 shall be applicable to remote assessments of diabetic ret-
10 inopathy that are furnished through the use of store-and-
11 forward technologies that provide for the asynchronous
12 transmission of health care information in single or multi-
13 media formats.

14 (c) INTERIM PAYMENT PENDING PUBLICATION OF
15 FINAL RULE.—For the period beginning 30 days after the
16 date of the enactment of this Act and ending on the date
17 the Secretary of Health and Human Services publishes a
18 final regulation to carry out section 1861(s)(2)(AA) of the
19 Social Security Act, as added by subsection (a), the Sec-
20 retary shall provide for payment of retinopathy assess-
21 ments furnished under such section during such period,
22 and assign such temporary HCPCS code as is necessary
23 to provide for such payment.

24 (d) STUDY ON REIMBURSEMENT FOR REMOTE AS-
25 SESSMENTS OF DIABETIC RETINOPATHY.—(1) Not later

1 than 1 year after the date of the enactment of this Act,
2 the Secretary of Health and Human Services shall conduct
3 a study on the costs incurred by health care providers to
4 provide remote assessment of diabetic retinopathy serv-
5 ices, including an analysis of—

6 (A) per-patient cost, and

7 (B) start-up and administrative costs.

8 (2) Not later than 2 years after the date of the enact-
9 ment of this Act, the Secretary shall submit a report to
10 Congress on the study conducted under paragraph (1) and
11 shall include recommendations with respect to—

12 (A) the adequacy of reimbursements for remote
13 assessment of diabetic retinopathy under the medi-
14 care program; and

15 (B) whether the study under paragraph (1)
16 should be repeated, and if so, how frequently.

17 (e) EFFECTIVE DATE.—The amendments made by
18 subsection (a) shall apply to assessments performed on or
19 after the date that is 30 days after the date of the enact-
20 ment of this Act.

21 **SEC. 4 MEDICAID COVERAGE OF REMOTE ASSESSMENT OF**
22 **DIABETIC RETINOPATHY.**

23 (a) REQUIREMENT.—Section 1905(a)(13) of the So-
24 cial Security Act (42 U.S.C. 1396d(a)(13)) is amended by

1 inserting “remote assessment of diabetic retinopathy (as
2 defined in section 1861(bbb)),” after “including”.

3 (b) EFFECTIVE DATE.—The amendment made by
4 subsection (a) shall apply to assessments performed on or
5 after the date of the enactment of this Act.

6 (c) STATE COMPLIANCE.—In the case of a State plan
7 for medical assistance under title XIX of the Social Secu-
8 rity Act which the Secretary of Health and Human Serv-
9 ices determines requires State legislation (other than legis-
10 lation authorizing or appropriating funds) in order for the
11 plan to meet the additional requirement imposed by the
12 amendments made by subsection (a), the State plan shall
13 not be regarded as failing to comply with the requirements
14 of such title solely on the basis of its failure to meet this
15 additional requirement before the first day of the first cal-
16 endar quarter beginning after the close of the first regular
17 session of the State legislature that begins after the date
18 of the enactment of this Act. For purposes of the previous
19 sentence, in the case of a State that has a 2-year legisla-
20 tive session, each year of such session shall be deemed to
21 be a separate regular session of the State legislature.

1 **SEC. 5. MOBILE DIABETIC RETINOPATHY SCREENING**
2 **PILOT PROGRAM.**

3 Title III of the Public Health Service Act (42 U.S.C.
4 241 et seq.) is amended by inserting after section 317S
5 the following:

6 **“SEC. 317T. MOBILE DIABETIC RETINOPATHY SCREENING**
7 **PILOT PROGRAM.**

8 “(a) IN GENERAL.—

9 “(1) ESTABLISHMENT.—The Secretary shall es-
10 tablish a grant program, to be known as the ‘Mobile
11 Diabetic Retinopathy Screening Pilot Program’, to
12 make grants to 5 eligible entities for the purpose of
13 establishing mobile diabetic retinopathy screening
14 programs.

15 “(2) USE OF FUNDS.—The Secretary may not
16 make a grant to an eligible entity under this section
17 unless the entity agrees to use the grant to carry out
18 a project consisting of the design, demonstration,
19 and implementation of a mobile diabetic retinopathy
20 screening program.

21 “(3) MAXIMUM AMOUNT.—The Secretary may
22 not make any grant under this section in an amount
23 that is greater than \$1,000,000 for any year.

24 “(4) SOLICITATION OF APPLICATIONS.—Not
25 later than 90 days after the date on which amounts
26 are first made available to carry out this section, the

1 Secretary shall publish a notice of solicitation for ap-
2 plications for grants under this section that specifies
3 the information to be included in each application.

4 “(5) APPLICATIONS.—To seek a grant under
5 this section, an eligible entity shall submit an appli-
6 cation to the Secretary at such time, in such form,
7 and containing such information as the Secretary
8 may require.

9 “(6) PRIORITY.—In making grants under this
10 section, the Secretary shall give priority to any ap-
11 plicant that—

12 “(A) has experience in evaluating diabetic
13 retinopathy using telecommunications equip-
14 ment, including store and forward technologies;
15 and

16 “(B) proposes to serve rural, impoverished,
17 underserved, minority, and remote populations.

18 “(7) CONGRESSIONAL NOTIFICATION.—The
19 Secretary may not make a grant under this section
20 unless, not less than 3 days before making the
21 grant, the Secretary provides notification of the
22 grant to the appropriate committees of the Congress.

23 “(b) EVALUATION AND REPORT.—

24 “(1) EVALUATION.—Not later than 3 years
25 after making the first grant under this section, the

1 Secretary shall convene an advisory committee for
2 the purposes of conducting an evaluation of the Mo-
3 bile Diabetic Retinopathy Screening Pilot Program.
4 In conducting the evaluation, the advisory committee
5 shall determine—

6 “(A) whether the Program has been effec-
7 tive in increasing early detection of diabetic ret-
8 inopathy, whether preventative measures taken
9 upon such detection have been effective in de-
10 creasing the prevalence and severity of diabetic
11 retinopathy, and whether these findings war-
12 rant continued or expanded support of the Pro-
13 gram; and

14 “(B) whether the program may serve as a
15 useful model for similar screening programs to
16 detect complications associated with diabetes,
17 high blood pressure, high cholesterol, and other
18 chronic conditions.

19 “(2) REPORT.—Not later than 54 months after
20 making the first grant under this section, the Sec-
21 retary shall submit a report to the appropriate com-
22 mittees of the Congress containing the results of the
23 advisory committee’s evaluation.

24 “(c) DEFINITIONS.—In this section:

1 “(1) ADVISORY COMMITTEE.—The term ‘advi-
2 sory committee’ means the advisory committee con-
3 vened under subsection (b).

4 “(2) ELIGIBLE ENTITY.—The term ‘eligible en-
5 tity’ means—

6 “(A) a hospital (as defined in section
7 1861(e) of the Social Security Act); or

8 “(B) a State, an institution of higher edu-
9 cation, a local government, a tribal government,
10 a nonprofit health organization, or a community
11 health center receiving assistance under section
12 330.

13 “(3) MOBILE DIABETIC RETINOPATHY SCREEN-
14 ING PROGRAM.—The term ‘mobile diabetic retinop-
15 athy screening program’ means any program—

16 “(A) that offers remote assessment of dia-
17 betic retinopathy as described in Section
18 1861(bbb) of the Social Security Act;

19 “(B) whose patients primarily reside in
20 rural, underserved, and remote areas; and

21 “(C) that is mobile (as determined by the
22 Secretary).

23 “(4) PROGRAM.—The term ‘Program’ means
24 the Mobile Diabetic Retinopathy Screening Pilot
25 Program established under this section.

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—

2 “(1) IN GENERAL.—There is authorized to be
3 appropriated to carry out this section (except for
4 subsection (b)) \$5,000,000 for each of fiscal years
5 2006 through 2010.

6 “(2) EVALUATION AND REPORT.—There are
7 authorized to be appropriated to carry out sub-
8 section (b) such sums as may be necessary.”.

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